CODES OF ETHICS

Ethical Guideline for Researches on Tissue and Organ Transplantation

Introduction

Considering the ever-increasing and multilateral approach to development and advancement of the transplantation in Iran and noting the recent technical and scientific advancements in this regard, and emphasizing on the necessity of scientific researches in this field, observing of the ethical principles in such researches is evident and essential. Human tissues and organs can be used for therapeutic, educational and research purposes. This guideline mentions to the essential ethical principles which should be considered in the researches on tissue and organ transplantation. This ethical guideline consists of two parts containing general and special articles.

General Guideline

Researches on tissue and organ transplantation are researches using human materials aimed to advancement of the science of transplantation. Human materials include organ, tissue, endocrine secretions, or waist material of alive or dead body, fetus, or placenta.

1- All researches in the field of tissue or organ transplantation should be done whit consideration of all of the articles of "The Ethical Guideline for Researches on Tissue and Organ Transplantation".

2- The purpose of research should be scientific advancement and in accordance with the goals of national health system, and should not be for financial or commercial purposes.

3- All researches in the field of tissue or organ transplantation should be approved by the related ethical committees of the university or research center.

Note: Ethical surveillance and assessment of the ethical committees with regular time intervals and thorough the course of research is essential.

4- For ethical approval, all donations of organs should be made with the donor's informed consent

Note: The obtained consent should be based on the research purposes.

5- Interests and requests of the participant(s) should be placed above those of researchers.

Note: In special conditions in which the public health depends on such researches, and avoiding of such researches would be harmful for the community, such researches may be done with approval of the national committee of research ethics.

6- All of personal information obtained from the participants in the research, and gathered and recorded through the course of research, should be considered confidential, and confidentiality should be observed according to the related articles in the " General Guideline of Ethics in Research"

7- Appropriate tests and screening should be performed on the donor and donated organs for preventing of transmission of infectious diseases.

8- No cost should be imposed to the donor in any stages of the research.

9- The researcher or the sponsor organization should compensate any possible harm. Including physical, financial or spiritual harms, to the participant in transplantation research, according to domestic law and opinion of related authorities.

10- An agreement regarding the mean and level of informing the participants about the results of the research should be made and mentioned in the consent.

11- Some transplantation researches may result in invention or production of therapeutic products or techniques which could be used commercially. Therefore, copy right of research results should be approved and supported.

12- In addition to considering all of ethical principles. The research should be conducted only by scientifically

and technically qualified team and the center or organization in which the research is being conducted should have appropriate facilities for research and prevention and treatment of possible complications.
13- Sending tissues or organs to foreign countries for common researches, is permitted only with approval of the "National Committee of Research Ethics".
Note 1: Common researcher with foreigner financial or scientific sponsor, if do not require sending tissues or organs to foreign countries, are permitted.
Note 2: For using the tissues or organs of foreigner persons in transplantation researches, the Approval of the "National Committee of Research Ethics" is necessary.
14- The researcher should use the organs and tissues which are dedicated to research and should not dismiss them. If any kind of carelessness is proven, the researcher should compensate the possible losses.
15- Considering the shortage of organ and tissue for transplantation in Iran, the therapeutic uses should take priority and research uses should not reduce the rate and quality of the therapeutic uses.
16- For using of tissues and organs stored in the tissue and organ banks, the donor should permitted the research use in the consent.
Note: If the donor did not mentioned to the means of use, it can be used for research purposes, only if there is no request for therapeutic use.

Special Guidelines

Chapter 1: Cadaver Donor Transplantation
1-1- In the cases of using of the organs or tissues of dead persons for transplantation, its necessity should be approved by the ethics committee.
Note1: Currently, the system of obtaining consent for using the cadaver for research in Iran is based on opting-in. So, the consent of person before death or the consent of his or her representative is necessary. In the transplantation researches the consent should be based on opting-in, even if this would be changed for therapeutic purposes.
Note2: When one is opposed to donating his or her organs or tissues, his or her representative can not permit it after his or her death.
1-2- Researches which are being conducted in governmental or non-governmental research centers, should be approved by the ethical committee of that center and an ethical committee at a higher level (i.e. ethical committee of the related university for the research centers, ethical committee of province for the universities of cities other than the centers of provinces, and the national committee of research ethics for the universities of the centers of the provinces)
1-3- In the cases of using tissues or organs of a person after brain death, all the related laws and regulations and the protocol of confirmation of brain death should be considered.
1-4- At the time of removal of tissues or organs from the cadaver until the time of burying of the cadaver, the regular and jurisprudical respects to the cadaver and the removed tissues or organs is essential.

Chapter 2: Living Donor Transplantation
2-1- The requests and interests of the donor should always take priority over those of the recipient of the transplant and obtaining a written informed consent from the donor is imperative.
Note 1: The participant should be informed about the methodology and purpose of research and type and amount of tissue or organ which would be removed and all of related risks, in written form.
Note 2: In the cases of absolute necessity, under observance and approval of ethical committee of the university, one can use the pair organs whose removal will not greatly alter the physiologic functions, for

research purposes. The donor should be lifetime insured and all of the related harms should be compensated.
Note 3: Vital organs such as brain, heart, etc or paired organs whose removal will greatly alter the quality of life such as eye, should not be used for research purposes.
2-2- The obtained tissues or organs should only be used for the researches which are informed to the donor and the related informed consent is obtained.
2-3- Surplus or waste tissues remaining from diagnostic and therapeutic procedures or surgeries other than transplantation surgeries, with considering the confidentiality and after approval of the ethical committee, can be used for transplantation researches, without obtaining an informed consent, unless the owner or the tissue has been notified his or her disagreement.
Note 1: The owner of tissue should be informed about and implicitly agree with the use of his or her tissues for the research purposes.
Note 2: Refusal of the above mentioned person should not have any effects on his or her diagnostic or therapeutic procedures.
2-4- The Any other risks, such as prescription of immunosuppressive drugs or … should not be imposed to the donor of tissue or organ, unless it would be necessary fir his or her health.
2-5- When after removal of tissue or organ the donor needs to follow up or specific therapies in determined intervals, it should be prepared for him or her free of charge.
Note 1: Researches with human subject should be covered by insurance.
Note 2: When there is no need to follow up, if the patient returns after a time interval with a complication which is related to tissue or organ donation, compensation of related costs should be done by the researcher, sponsor organization, or the insurance company.
2-6- The obtained tissue or organ belongs to the donor, so the donor can refuse or withdraw his or her consent till the irreversible stage of the research.
Note: If the donor withdraws from the experiment, he or she should not pay for the resulted costs.
2-7- Financial incentives or special advantages should not be used for encourage persons for organ or tissue donation in the transplantation researches with live donor.
2-8-Children, mental retarded persons, mental disabled persons and other special groups who possibly have not competence for informed decision making, should not be donor of tissue or organ in transplantation researches.
Chapter3: Issues related to the recipient of organ or tissue
3-1- If the recipient is a patient who needs to the organ or tissue, the best available therapeutic methods should be used for him or her and access to treatment should not b banned for research purposes.
3-2- Children, mental retarded persons, mental disabled persons and other special groups who possibly have not competence for informed decision making, should only be recipient of tissue or organ in transplantation researches (with direct therapeutic benefit for them) and non-therapeutic researches on these groups is forbidden.

Chapter4: Using organs or tissues obtained from human embryo or fetus
Definitions: Between 2nd and 8th week after conception, the product of conception is considered an embryo, after the 8th week, it is considered a fetus till birth, and after that it is considered a neonate. Ethical standard that are affirmed in this regard include:
1- Respect to humanity and dignity of embryo and fetus
2- Prevention of any type of commercial use
3- Necessity of the research
4- Obtaining consent from parents and considering the mother's rights
5- No prior planning for using tissues or organs of the embryo or fetus

6- Obtaining informed consent and considering the obligations to the recipient
7- Approval of ethics committee
8- Informed participation of the members of research team
9- Confidentiality and secrecy of personal information
10- Research in cases which are in contrast with jurisprudical rules (according to related authorities) or are harmful for the mother or fetus, or are in contrast with domestic laws, is forbidden.
4-1- The researches on transplantation of tissues or organs of embryo of fetus should be approved by the "National Committee of Research Ethics" and after the approval, ethical surveillance should be done by the ethical committee of the related university or research center. Reports should be sent regularly to the "National Committee of Research Ethics".
Note 1: Conductions such researches is only permitted in the universities or governmental research centers and under the surveillance of the ministry of health
Note 2: The articles of the "Ethical Guideline for Researches on Gamete and Fetus" should be considered in such researches.
4-2- For using the organs and tissues of fetus in the transplantation researches, following obligations are necessary:
A- Scientific approval of the research, follow up, Control and subsequent assessments by the research institute and related authorities.
B- Animal experiments must show successful results
C- Trials in human patients will commence only on those patients where no other form of treatment is available and where, in the absence of the transplant, the patient is likely to suffer relentless deterioration in his or her health with fatal termination.
D- Such trials should be carried out only at institutions having appropriate facilities needed for performing such researches.
4-3- Conducting research using embryo or fetus material for financial purposes id forbidden.
4-4- Performing abortion (in human) for research purposes and for using the tissues or organs is forbidden.
4-5- No research is permitted on the premature neonate, unless it involves no harm for the health of the neonate and consent of the legal representative with considering the interests of the neonate is obtained.
4-6- Keeping the nonviable fetus alive with the mechanical instruments, for using his or her tissues or organs in research is forbidden.
4-7- Research on the aborted fetus (for treatment or spontaneous) is permitted with the informed written consent from the parents and considering ethical issues related to the obtaining organ and tissue from the cadaver and considering jurisprudical and legal obligations.
Note 1: When access to one parent is impossible, the consent of the other one is sufficient.
Note 2: The placenta and other contents of the uterus belong to the mother and her consent for using them is necessary and sufficient.
4-8- No research is permitted on the organs or tissues of the fetus whose parents are unknown or are not capable to give informed consent, unless with the approval of the "National Committee of Research Ethics".
4-9- In addition to informed written consent of parents for doing research, legal approval and written consent for termination of pregnancy and written consent for diagnostic tests (if are needed) on the embryo, fetus or mother, should be obtained.
4-10- Decision making regarding termination of pregnancy should not in any way be influenced by the subsequent research usage of the tissues or organs of the fetus. In therapeutic abortion the timing of the abortion should only be based on the conditions of mother and considering her health, and changing the timing for research usage of organs and tissues is not permitted.
4-11- The decision makers for abortion should not be party of subsequent usage of embryonic or fetal tissue

for research.
4-12- Decision-making regarding abortion should be made by persons who have no job relation with the organization in which the research is being conducted.
4-13- Screening of transmissible diseases among the donor fetus and his or her mother is necessary.
4-14- Financial relation between the donor and the recipient in the researches on transplantation of organs and tissues of embryo or fetus is forbidden.
4-15- Tissues and organs obtained from embryo or fetus can be stored in the biobanks for future use only with consent of the legal representative.
4-16- Use of umbilical cord blood from an aborted fetus or live neonate is permitted only with informed consent of the mother and ensuring that no harm will occur to the neonate. Clamping of the umbilical cord should be performed timely and without delay.
4-17- Decision making regarding using tissues and organs of epencephalic fetus for research purposes should be done only after absolute confirmation of death and with considering all of above mentioned articles regarding cadaver donor transplantation.
4-18- Priority-setting regarding the researches on transplantation of organs and tissues of embryo or fetus should be done by the national committee of research ethics for optimal use of available tissues and organs.
All the members of the research team should be informed regarding the nature of the research and the tissues and organs which are being used in the research. Each of them has the right of withdrawal from participation in the research if his or her withdrawal dos not halt the research.
Some references are used in the initial compiling of this guideline. (89-102)